

## **DETAILED ACTION**

### ***Response to Amendment***

The amendment filed on 10/18/11 has been entered in the case. Claims 41-49 are pending for examination and claims 1-40 have been cancelled.

### ***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Noted that a member 180 is a splittable bond, however, the specification does not depict the limitation "the bond proximal end initially spaced a first initial distance from the first proximal end and a second initial distance from the second proximal end, wherein the distances from the proximal ends of first and second flexible catheters to the bond proximal end may be increased by splitting the splittable bond" in lines 7-10 of claim 1; the limitation "the first proximal passage ... having a length less than the first initial distance such that the first flexible catheter extends from a first proximal opening of the hub member, the second proximal passage ... having a length less than the second initial distance such that the second flexible catheter extends from a second proximal opening of the hub member" in lines 13-18 of claim 1; and the limitation "wherein the bond distal end is initially spaced a third initial distance from the first distal end and a fourth initial distance from the second distal end, and wherein the third and fourth initial distances are different from one another." of claim 46.

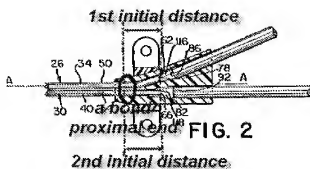
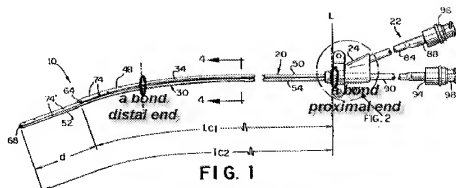
### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 41-42, 44-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ash (US 5,947,953) in view of Sisley et al. (US 4,405,313) and either Raulerson (US 4,037,599) or Zia et al. (US 2002/0120224).**

**Regarding claim 41,** Ash discloses a multiple catheter assembly, comprising: a first flexible catheter 26 having a first distal end 64 configured for implantation into a patient, see Fig. 5; and a first proximal end 62 configured/capable of attaching (via hub and tunnel 116) to a first medical element 86 or 96; a second flexible catheter 30 having a second distal end 68 configured for implantation into a patient, see Fig. 5; and a second proximal end 66 configured/capable of attaching (via hub and tunnel 118) to a second medical element 82 or 98, the first and second flexible catheters 26, 30 attached to one another via a splittable bond 46 extending from a bond distal end to a bond proximal end, the bond proximal end initially spaced a first initial distance from the first proximal end and a second initial distance from the second proximal end, see Figs. 1-2 markup below, wherein the distances from the proximal ends of first and second flexible catheters to the bond proximal end may be (or capable of increasing) increased by splitting the splittable bond, for example: the membrane 46 is constructed to split easily when the first and second catheters 26, 30 are forcibly separated from each other, see col. 6, lines 42-44.; and a hub member 24 defining a distal passage (distal hub opening) configured to receive the attached first and second flexible catheters 26, 30 and first and second proximal passages intersecting the distal passage at an intersection, the first proximal passage configured for passage of the first flexible catheter 26; the second proximal passage configured for passage of the second flexible catheter 30. Noted that the first and second flexible catheter is capable of performing a function such as the lengths of the first and second catheters extending and passing through the first and second proximal end passages, (also see Fig. markup of Ash as modified by Sisley below).

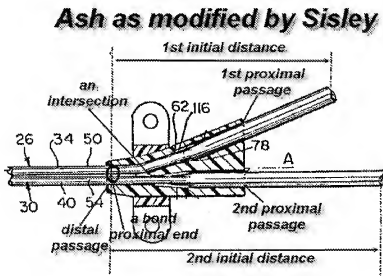


As seen in Fig. 2 above, Ash does not disclose that the first proximal passage having a length less than the first initial distance such that the first flexible catheter extends from a first proximal opening of the hub member, the second proximal passage having a length less than the second initial distance such that the second flexible catheter extends from a second proximal opening of the hub member. In other words, the first and second flexible catheters 26, 30 must be extended and passed through and beyond the proximal end of the hub member 24 so that the first and second proximal passages each having a length less than the first and second initial distances.

Sisley discloses a multiple catheter assembly comprising: first and second catheters 12, 14; a hub member 22; wherein the first and second flexible catheters 12, 14 extending and passing beyond the hub member 22 and connected with first and second medical elements (i.e. connectors 24, 26).

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Ash with first and second catheters extending and passing through a hub member, as taught by Sisley, so as the lengths of the first and second initial distances greater than the first and second proximal passages will bring the benefit of eliminating splitting of the catheter tubes.

As seen in Fig. markup below, Ash in view of Sisley discloses that the first and second flexible catheter 26, 30 extending and passing through the hub 24, therefore, the first initial distance (i.e. defined a distance in between the bond proximal end to the first proximal end of the first catheter tube 26) and the second initial distance (i.e. defined a distance in between the bond proximal end to the second proximal end of the second catheter tube 30) having lengths greater than the hub 24, and greater than the first and second proximal passages.



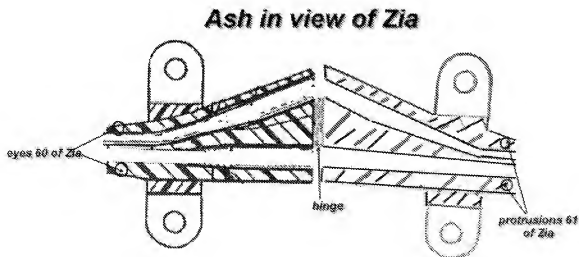
As to the further limitation of claim 41, that "the hub member is configured such that the hub member is longitudinally adjustable along the flexible catheters to position the bond proximal end proximate to the hub member intersection", this is considered as a functional limitation which only requires the capability of performing the claimed function. In this case, although Ash in view of Sisley is silent that the hub member is longitudinally adjustable along the flexible catheters to position the bond proximal end proximate to the hub member intersection. However, the combination of Ash in view of Sisley and either Raulerson or Zia, will bring the benefit such as the hub member is longitudinally adjustable along the flexible catheters to position the bond proximal end proximate to the hub member intersection. See below for more details.

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Raulerson teaches a hub device comprising: a hub member 12 including a hinge line 20 such that folding of one hub portion relative to this hinge line into mating engagement with the other hub portion so that the hub member is opening and closed positions.

Giving such teaching by Raulerson, a person having ordinary skill in the art would have easily recognizes that modifying the device of Ash with providing an open/closed structure in a hub device, as taught by Raulerson, would provide the benefit of adjustability (i.e. detachable or attachable) of the catheters in the support member in certain situations. For example: the hub member 24 of Ash including a hinge member 20 of Raulerson, so as the hub member 24 of Ash is able to open and close, and the hub member is longitudinally adjustable along the flexible catheters to position the bond proximal end proximate to the hub member intersection.

Alternatively, Zia discloses a hub device/tube holder 50 comprising: a first portion 51 connecting to a second portion 52 by a hinge 53; eyes 60; protrusion 61; wherein the eyes 60 provided in first mating portion will receive a pair of hooks/protrusion 61 provided on second portion, which will attached/fixedly and removably for a catheter. In other the words, the operator can provide the hub device or tube holder 50 attached and detached to the catheter by opening (unhook protrusions 61 from eyes 60) or closing (hook protrusions 61 into eyes 60).



Giving such teaching by Zia, a person having ordinary skill in the art would have easily recognizes that modifying the device of Ash with providing an open/closed structure (i.e. protrusions, eyes and a hinge line) in a hub device at a portion located in between two proximal passage ways of the hub device, see Fig. markup above, as taught by Zia, would provide the benefit of detaching/attaching catheter to the hub device. Thereby, the hub member is longitudinally adjustable along the flexible catheters to position the bond proximal end proximate to the hub member intersection.

**Regarding claim 42**, Ash discloses that the portions of the first and second flexible catheters initially attached to one another via the splittable bond each have a semicircular cross-section, see Fig. 4F. Ash does not show in Figs. 1a that the first and second proximal ends each have a circular cross-section, however, Ash discloses that the lumen 28, 32 (i.e. including first and proximal ends) formed circular shaped, see col. 7, lines 30-39. Furthermore, Sisley discloses the first and second proximal ends each have a circular cross section, see Fig. 3.

**Regarding claim 44**, Ash discloses that the first flexible catheter 26 has a first distal end region, between the bond distal end and the first distal end 64 of the first flexible catheter 26, see Fig. 3 markup below; the second flexible catheter 30 has a second distal end region between the bond distal end and the second distal end 68 of the second flexible catheter, see Fig. 3 markup below, and the first and second distal end regions are separate from one another.

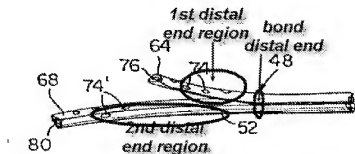
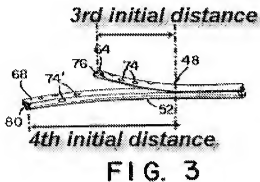


FIG. 3

**Regarding claim 45**, Ash discloses that the first and second distal end regions each define side apertures 74, 74' extending through a respective surface thereof.

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**Regarding claim 46,** Ash discloses that the bond distal end is initially spaced a third initial distance from the first distal end 64 and a fourth initial distance from the second distal end 68, and wherein the third and fourth initial distances are different from one another, see Fig. 3 markup below.



**Regarding claim 47,** Ash discloses that each of the first and second proximal ends includes respective connection members 96 and 98; or Sisley discloses each of the first and second proximal ends includes respective connection members 24 and 26.

**Regarding claim 48,** Ash discloses that each connection member includes a compression fitting, see col. 12, lines 27-31.

**Regarding claim 49,** since Ash in view of Sisley and either Raulerson or Zia, the flexible catheters 26, 30 are attached/detached to/from the hub member, therefore, Ash in view of Sisley and either Raulerson or Zia discloses the distal passage, or the first and second proximal passages, or the distal passage and the first and second proximal passages are configured to (or capable of) have a friction fit with respect to flexible catheters.

**Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ash in view of Sisley and either Raulerson or Zia et al. and further in view of Cazal (US 5,800,414).**

Ash in view of Sisley and Raulerson/Zia discloses the invention substantially as claimed invention. Ash discloses the spittable member 46 formed of material that easy tearing but does not specifically discloses forming of an adhesive.

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Cazal discloses a similar device, in which the first and second catheters are splittably joined to each other by adhesive 14 or 20. It is noted that the adhesive 14 or 20 is capable of being splitted if using sufficient force to tear it.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Ash in view of Sisley and Raulerson/Zia, with an adhesive, as taught by Cazal, if one wished to easily join or tear the two catheters.

### ***Response to Arguments***

Applicant's arguments with respect to newly added claims 41-49 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/QUYNH-NHU H VU/  
Examiner of Art Unit 3763